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**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
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| MUTUAL PHARMACEUTICAL COMPANY, INC., et al.,<br><br>Plaintiffs,<br><br>v.<br><br>WATSON PHARMACEUTICALS, INC., et al.,<br><br>Defendants. | Civil Action No. 09-5421(GEB)(TJB)<br><br>**PLAINTIFFS' RESPONSIVE STATEMENT OF MATERIAL FACTS TO DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S STATEMENT OF UNDISPUTED MATERIAL FACTS** |

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Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. (collectively, "Plaintiffs"), pursuant to Local Civil Rule 56.1(a), respectfully submit their Responsive Statement of Material Facts ("Responsive Statement") to Defendant West-Ward Pharmaceutical Corp.'s ("Defendant") Statement of Undisputed Material Facts in Support of Its Motion for Summary Judgment. Mutual submits this Responsive Statement, along with its Opposition to West-Ward's Motion for Summary Judgment and Supplemental Statement of Disputed Material Facts, in support of its request that the Court deny West-Ward's Motion for Summary Judgment based on its assertion of an unclean hands defense.

## RESPONSIVE STATEMENT OF MATERIAL FACTS

1. Agree.

2. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 2 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶ 5(a).

3. Plaintiffs agree that Defendant's colchicine tablet tablets are listed in the National Drug Code Director under NDC 00143-1201. Plaintiffs lack knowledge or information sufficient to agree or disagree with the remaining statements in paragraph 3 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶ 5(b).

4. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 4 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶ 5(b).

5. Plaintiffs agree that Defendant is a generic drug company. Plaintiffs disagree that Defendant does not market, advertise, or promote its colchicine tablets in the customary sense of those terms. Defendant uses the Price Lists and

Wholesaler Ordering Systems – two specialized marketing channels that are commonly used by pharmaceutical companies – to market, advertise, and promote its colchicine tablets. Exhibit H to the concurrently filed Declaration of N. Kottahachchi, Defendant West-Ward's Responses to Plaintiff's First Set of Requests for Admission at Responses Nos. 2, 3, 6, and 7. Plaintiffs lack knowledge or information sufficient to agree or disagree with the remaining statements in paragraph 5 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶ 5(c).

6. Agree.

7. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 7 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶¶ 5(d)-(f) .

8. Plaintiffs agree that Price Lists and Wholesaler Ordering Systems report Therapeutic Equivalency Ratings, as published in FDA's Orange Book of Approved Drug Products. Plaintiffs lack knowledge or information sufficient to agree or disagree with the remaining statements in paragraph 8 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶¶ 5(g) and (h).

9. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 9 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶ 5(i).

10. Plaintiffs agree that Mutual Pharmaceutical Company, Inc. is a subsidiary of URL Pharma, Inc., and an affiliate to United Research Laboratories, Inc.

11. Agree.

12. Agree.

13. Agree.

14. Agree.

15. Disagree. Plaintiffs allege that Defendant's "colchicine product labels, instructions for use, commercial advertising and promotions, including the placing of the aforementioned misleading information in advertising channels including Price Lists, Wholesaler Ordering Systems, drug ordering systems used by drug store chains, and Internet websites, constitute false and misleading descriptions or representations of fact that their colchicine products are safe, effective and/or FDA-approved, and that the safety and warning information provided with [Defendant's] unapproved colchicine products is complete." Complaint, at ¶143.

16. Agree.

17. Agree.

18. Agree.

19. Agree.

20. Agree.

21. Plaintiffs agree that they ceased distributing unapproved colchicine tablets in 2006. Plaintiffs lack knowledge or information sufficient to agree or disagree with the remaining statements in paragraph 21 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶¶ 5(j) and (k).

22. Agree.

23. Agree.

24. Plaintiffs agree that they ceased distribution of unapproved drugs in 2006. Plaintiffs further agree that have sought and will continue to seek FDA-approval for drugs they intend to sell.

25. Plaintiffs agree that profit is part of their business model.

26. Plaintiffs agree that AR Holding Company, Inc. and AR Scientific, Inc. were formed on August 13, 2005 and December 8, 2004, respectively.

27. Plaintiffs agree that they obtained FDA approval in August 2005 for quinine sulfate. Plaintiffs agree that they filed a complaint for false advertising and unfair competition in the Central District of California against certain distributors of quinine sulfate.

28. Agree.

29. Agree.

30. Plaintiffs agree that they contacted the FDA about the distribution of unapproved colchicine after submitting their NDA to the FDA.

31. Plaintiffs agree that FDA action in both approving its colchicine product and removing unapproved colchicine from the market was a factor in their business planning.

32. Agree.

33. Plaintiffs agree that their marketing literature contained the excerpts found in paragraph 33 of Defendant's statement of undisputed material facts.

34. Agree.

35. Agree.

36. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 36 of Defendant's statement of undisputed material facts.

37. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 37 of Defendant's statement of undisputed material facts. Plaintiffs are not privy to the FDA's decision making process regarding enforcement actions against parties distributing unapproved drugs, including unapproved colchicine.

38. Disagree. *See, e.g.,* Exhibit F to the Kottahachchi Decl., "FDA Acts to Improve Drug Safety and Quality," (June 8, 2006) ("'Right now, many unapproved drugs represent a public health threat because consumers wrongly

assume that these widely marketed and available drugs are approved and have been found to be safe and effective by the FDA,' said Acting FDA Commissioner Dr. Andrew von Eschenbach"); *see also* Exhibit G to the Kottahachchi Decl., "Questions and Answers About FDA's Enforcement Action Against Unapproved Injectable Colchicine Products," (February 6, 2008) ("Like all other unapproved drugs, *colchicine tablets that are marketed without FDA approval could be subject to FDA enforcement at any time. Accordingly FDA strongly encourages the manufacturers of those products to pursue FDA approval.*") (emphasis added).

39. Plaintiffs agree that the FDA took enforcement action against injectable colchicine in 2008 and removed it from the market. Plaintiffs further agree that the Federal Register is accurately quoted by Defendant in paragraph 39. Plaintiffs disagree that the FDA in the Federal Register notice "expressly noted that the *oral* form of colchicine is substantially safer than the *injectable* form of colchicine."

40. Plaintiffs agree that in 2008 the FDA website contained the language quoted in paragraph 40 of Defendant's statement of undisputed material facts.

41. Plaintiffs agree that Defendant has provided an accurate excerpt from the FDA's Marketed Unapproved Drugs – Compliance Policy Guide in 2006. A related footnote to the excerpt provided by Defendant also provides: "Firms are reminded that this [Compliance Policy Guide] does not create any right to a grace period; the length of the grace period, if any, is solely at the discretion of the Agency. *For instance, firms should not expect any grace period when the public health requires immediate removal of a product from the market, or when the Agency has given specific prior notice in the Federal Register or otherwise that a drug requires FDA approval*." Exhibit A to the Kottahachchi Decl., "Guidance for FDA Staff and Industry: Marketed Unapproved Drugs – Compliance Policy Guide," p. 6, fn. 11 (2006) (emphasis added).

42. Plaintiffs agree that they contacted the FDA about the distribution of unapproved colchicine after receiving FDA approval for COLCRYS®.

43. Plaintiffs agree that they filed a complaint for false advertising and unfair competition against distributors of unapproved colchicine in the U.S. District Court for the Central District of California, which also granted a preliminary injunction in the *Ivax* case.

44. Agree.

45. Agree.

46. Agree.

47. Agree.

48. Agree.

49. Agree.

50. Plaintiffs agree that they contacted the FDA about the distribution of unapproved colchicine after Plaintiffs' motion for preliminary injunction was denied.

51. Plaintiffs lack knowledge or information sufficient to agree or disagree with the statements in paragraph 51 of Defendant's statement of undisputed material facts. *See* Mutual's Rule 56(f) Affidavit ¶¶ 5 (b) and (c).

52. Plaintiffs agree that the FDA sent warning letters to Vision Pharma LLC and Sunrise Pharmaceutical, Inc. regarding the distribution of unapproved colchicine. These letters are attached as Exhibits B and D to the Kottahachchi Decl.

Dated: August 23, 2010

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